(d) *Other indications.* The patient package insert may identify indications in addition to contraception that are identified in the professional labeling for the drug product.

(e) *Labeling guidance texts.* The Food and Drug Administration issues informal labeling guidance texts under § 10.90(b)(9) of this chapter to provide assistance in meeting the requirements of this section. A request for a copy of the guidance texts should be directed to the Center for Drug Evaluation and Research, Division of Metabolism and Endocrine Drug Products (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(f) *Requirement to supplement approved application.* Holders of approved applications for oral contraceptive drug products that are subject to the requirements of this section are required to submit supplements under § 314.70(c) of this chapter to provide for the labeling required by this section. Such labeling may be put into use without advance approval by the Food and Drug Administration.

[54 FR 22587, May 25, 1989]

§ 310.502 Certain drugs accorded new drug status through rulemaking procedures.

(a) The drugs listed in this paragraph (a) have been determined by rulemaking procedures to be new drugs within the meaning of section 201(p) of the act. Except as provided in paragraph (b) of this section, an approved new drug application under section 505 of the act and part 314 of this chapter is required for marketing the following drugs:

(1) Aerosol drug products for human use containing 1,1,1-trichloroethane.

(2) Aerosol drug products containing zirconium.

(3) Amphetamines (amphetamine, dextroamphetamine, and their salts, and levamfetamine and its salts) for human use.

(4) Camphorated oil drug products.

(5) Certain halogenated salicylanilides (tribromsalan (TBS, 3,4′,5-tribromosalicylanilide), dibromsalan (DBS, 4′, 5-dibromosalicylanilide), metabromsalan (MBS, 3, 5-dibromosalicylanilide), and 3,3′, 4,5′-tetrachlorosalicylanilide (TC–SA)) as an ingredient in drug products.

(6) Chloroform used as an ingredient (active or inactive) in drug products.

(7) Cobalt preparations intended for use by man.

(8) Intrauterine devices for human use for the purpose of contraception that incorporate heavy metals, drugs, or other active substances.

(9) Oral prenatal drugs containing fluorides intended for human use.

(10) Parenteral drug products in plastic containers.

(11) Sterilization of drugs by irradiation.

(12) Sweet spirits of nitre drug products.

(13) Thorium dioxide for drug use.

(14) Timed release dosage forms.

(15) Vinyl chloride as an ingredient, including propellant, in aerosol drug products.

(b) Any drug listed in paragraph (a) of this section, when composed wholly or partly of any antibiotic drug, must be certified under section 507 of the act or exempted from certification under section 507 of the act for marketing.

[62 FR 12084, Mar. 14, 1997]

EFFECTIVE DATE NOTE: At 62 FR 12084, Mar. 14, 1997, § 310.502 was revised, effective Apr. 14, 1997. For the convenience of the user, the superseded text is set forth as follows:

§ 310.502 Intrauterine devices for human use for the purpose of contraception.

(a) *New drug status of certain intrauterine devices for human use for the purpose of contraception.* (1) The Food and Drug Administration has become aware of the increased clinical use for the purpose of contraception of intrauterine devices (IUD's) that incorporate heavy metals, drugs, or other active substances. The amount of local irritation caused by such active materials has been reported as being correlated, in animal studies, to the efficacy of such devices in achieving their contraceptive effect. Several investigators have reported different pregnancy rates which appear to be dependent on the type of metal used and/or the amount of exposed surface of the metal. Drugs have been incorporated with otherwise inert intrauterine devices to increase the contraceptive effect, decrease adverse reactions, or provide increased medical acceptability.

(2) Intrauterine devices used for the purpose of contraception and incorporating heavy metals, drugs, or other active substances to increase the contraceptive effect, to decrease adverse reactions, or to provide